

II. Claims 1, 3, and 7, drawn to method of preventing the development of an autoimmune disease with a B7.2 protein, classified in Class 424, subclasses 184.1 and 810.

III. Claims 10-15, drawn to method of prolonging acceptance of an engrafted tissue with an anti-CD28 antibody, classified in Class 424, subclass 137.1; Class 514, subclass 885.

IV. Claims 10-11, and 16, drawn to method of prolonging acceptance of an engrafted tissue with an a B7.2 protein, classified in Class 424, subclass 184.1; Class 514, subclass 885.

V. Claims 17-21, 23-29, and 31, drawn to a pharmaceutical composition wherein the CD28 agonist is an antibody, classified in Class 424, subclass 137.1.

VI. Claims 17, 19, 22, 25, 27, and 30, drawn to a pharmaceutical composition wherein the CD28 agonist is a B7.2 protein, classified in Class 424, subclass 184.1.

The Applicant hereby elects to prosecute Group I (Claims 1-6 and 8-9), with traverse.

With regard to restriction Groups I and II, the Examiner has requested that the Applicant elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Claims from Group I were considered generic to a plurality of autoimmune diseases. The species enumerated were as follows.

- A) Diabetes
- B) Multiple sclerosis
- C) Myasthenia Gravis
- D) Hashimoto's thyroiditis
- E) Sjogren syndrome, or
- F) SLE.

The Applicant hereby elects species A (diabetes) from Group I.

B. Traverse

Applicant would like to pursue in this application the agonists of Claim 1. It has long been held that an Examiner may not reject a particular claim on the basis that it represents "independent and distinct" inventions. *See, In Re Weber, Soder and Boksay*, 198 USPQ 328, 331 (CCPA 1978) (emphasis added). *See also, In Re Haas*, 179 USPQ 623, 624, 625 (In Re Haas I) and *In Re Haas*, 198 USPQ 334-337 (In Re Haas II). The courts have definitively ruled that the statute authorizing restriction practice, *i.e.*, 35 U.S.C. §121, provides no legal authority to impose a restriction requirement on a single claim, even if the claim presents multiple independently patentable inventions. *See, In Re Weber, Soder and Boksay, In Re Haas I and In Re Haas II*. In the cases set forth above, the courts expressly ruled that there is no statutory basis for rejecting a claim for misjoinder, despite previous attempts by the Patent Office to fashion such a rejection. As noted in *In Re Weber, Soder and Boksay*:

The discretionary power to limit one applicant to one invention is no excuse at all for refusing to examine a broad generic claim -- no matter how broad, which means no matter how many independently patentable inventions may fall within it.

*See, In Re Weber, Soder and Boksay* at 334.

Alleging that a particular claim represents multiple "patentably distinct" inventions is a *de facto* rejection of the patentability of the claim, because the claim cannot issue as drafted. As the CCPA has noted:

As a general proposition, an applicant has a right to have each claim examined on the merits. If an applicant submits a number of claims, it may well be that pursuant to a proper restriction requirement, those claims will be dispersed to a number of applications. Such action would not affect the rights of the applicant eventually to have each of the claims examined in the form he considers to best

define his invention. If, however, a single claim is required to be divided up and presented in several applications, that claim would never be considered on the merits. The totality of the resulting fragmentary claims would not necessarily be the equivalent of the original claim. Further, since the subgenera would be defined by the examiner, rather than by the applicant, it is not inconceivable that a number of the fragments would not be described in the specification.

*See In Re Weber, Soder and Boksay, Supra.*

Instead of improperly imposing a restriction requirement on a given claim, the Office may limit initial examination to a "reasonable number" of species encompassed by the claim. *See*, 37 C.F.R. §1.146. This practice strikes an appropriate balance between the concerns of the Patent Office regarding administrative concerns and unduly burdensome examination, and the clear constitutional and statutory rights of an inventor to claim an invention as it is contemplated, provided the dictates of 35 U.S.C. §112 are complied with. *See*, the MPEP at 803.02. *See also*, *In Re Wolfrum* 179 USPQ 620 (C.C.P.A.) 1973) and *In Re Kuehl* 177 U.S.P.Q. 250 (C.C.P.A. 1973). Unlike a restriction requirement, a species election does not preclude an applicant from pursuing the original form of a claim in subsequent prosecution, nor does it force an applicant to file multiple divisional applications which are incapable of capturing the intended scope of the application. It should be clear that the added costs of filing and prosecuting multiple applications in the present case do not strike an appropriate balance between the administrative concerns of the Office and the Applicant's statutory rights as inventors.

Based on the discussion above, Applicant respectfully proposes that those restriction requirements which divide single claims into different groups have been made in error. Accordingly, Groups I and II (Independent claim 1) should be combined into a single group, Groups III and IV (Independent claim 10) should be combined into a single group, and Groups V and VI (Independent claims 17 and 25) should be combined into a single group.

Further, based on the Class and subclasses of the Groups as shown below, this re-grouping makes complete sense.

- I. Class 424, subclasses 137.1 and 810.
- II. Class 424, subclasses 184.1 and 810.
- III. Class 424, subclass 137.1; Class 514, subclass 885.
- IV. Class 424, subclass 184.1; Class 514, subclass 885.
- V. Class 424, subclass 137.1.
- VI. Class 424, subclass 184.1.

Applicant also respectfully requests that Groups I/II and V/VI be grouped together. Restriction is only proper when search and examination is "a serious burden on the examiner." See M.P.E.P. §803. The Applicant notes that claims in Group I/II and Group V/VI are classified in the same Class 424 and subclass 137.1. Also, the subject matter encompassed by these claims is related. Therefore, it is respectfully submitted that there would be no undue burden in searching prior art for both Group I/II (method) and Group V/VI (composition). To the contrary, it is natural and reasonable and desirable to search prior art in connection with examination of the claims in Groups I/II and V/VI; indeed, simultaneous prosecution of the groups would be more efficient.

Applicant thus requests that the Office reconsider this restriction requirement, and recombine Groups I/II and V/VI into a single group. In the alternative, should the Office maintain the split claims as noted above, then the Applicant respectfully requests that Groups I and V alone be combined into a single group.

Applicant believes that no fee is required for submission of this statement. However, if a fee is required, the Commissioner is authorized to deduct such fee from the

undersigned's Deposit Account No. 20-1430. Please deduct any additional fees from, or credit any overpayment to, the above-noted Deposit Account.

Respectfully submitted,

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